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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,696	06/19/2001	Lisle W. George	481.06	4037

7590 07/17/2002

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/884,696	George et al
Examiner	**Art Unit**
Portner	1645

-- ***The MAILING DATE of this communication appears on the cover sheet with the correspondence address*** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 19, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-33* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-33 are pending.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 12-15, 23-25, drawn to a peptides, polypeptides , or a cytotoxin protein defined by SEQ ID Nos 1 or 2, and specific peptides encoded by SEQ ID No 6 or 13, classified in class 530, subclass 350.

II. Claims 8-11, drawn to DNA of SEQ ID Nos 1,2, or fragments of SEQ ID NO 1 or 2, specifically SEQ ID NO 6 or 13, classified in class 536, subclass 23.1.

III. Claims 16-18, drawn to method of preventing infection, classified in class 424, subclass 190.1.

IV. Claims 19-22, drawn to a method of diagnosing infection, classified in class 435, subclass 7.1.

V. Claim 26 and 27 drawn to DNA of SEQ ID No 30, 18 classified in class 536, subclass 23.1.

VI. Claim 26 and 28 drawn to DNA of SEQ ID No 31, 32 classified in class 536, subclass 23.1.

VII. Claim 26 and 29 drawn to DNA of SEQ ID No 36, 37, classified in class 536, subclass 23.1.

VIII. Claims 30 and 31 drawn to an amino acid sequence of SEQ ID No 18 classified in class 530, subclass 350.

IX. Claim 30 and 32 drawn to an amino acid sequence of SEQ ID No 32 classified in class 530, subclass 350.

X. Claim 30 drawn to an amino acid sequence of SEQ ID No 37, classified in class 530, subclass 350.

XI. Claim 33 drawn to an amino acid sequence of SEQ ID No 38, classified in class 530, subclass 350.

2. Inventions II and I are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case, that the product as claimed can be made by another and materially different apparatus, specifically biochemical synthetic synthesis, or purification from the bacterial natural source.

3. Inventions I and VIII, IX, X, or IX are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention each protein evidences a different

sequence based upon SEQ ID NO, has a different chemical structure (amino acid structure) function which results in a different biological effect has separate utility such as immunogens, diagnostics, reagents for the purification of a different population of antibodies and for formulation of molecular image polymers specific to the protein. See MPEP § 806.05(d).

4. Inventions II and V, VI or VII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention Groups II, V, VI, and VII all differ in the number of nucleotides presented by each SEQ ID NO and encode proteins or polypeptides of differing sizes, structures and biological effects, each has separate utility such as for stimulating different populations of antibodies, and for detecting different genera, species and strains of pathogen. See MPEP § 806.05(d).

5. Inventions I and III or IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different

process of using that product, wherein the product can be used to immunize an animal, detect infection, produce antibodies for use in purification of the cytotoxin, and formulation of molecular image polymers.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. WO O1/161172 is cited to show the recombinant production of Moraxella bovis cytotoxin.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
July 10, 2002

MARK NAVARRO
PRIMARY EXAMINER